

NIH OFFICE OF EXTRAMURAL RESEARCH





The NIH Public Access Policy

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The NIH Public Access Policy Is Mandatory

In accordance with Division F Section 217 of PL 111-8 (Omnibus Appropriations Act, 2009), the NIH Public Access Policy (NOT-OD-08-033) remains a legislative mandate for FY 2009 and beyond.

The Director of the National Institutes of Health ("NIH") shall require in the current fiscal year and thereafter that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.





Implications of a Successful NIH Public Access Policy

Access to published research funded by the NIH will help advance science and improve human health

PUBLIC: Meets the public's expectation that articles based on NIH-funded research are publicly available. Provides information to understand health and disease.

INVESTIGATORS: Accessibility and integration of NIH-funded research results fosters discovery, new interdisciplinary collaborations, and the ability of all scientists to pursue NIH's research priority areas more competitively.

NIH: Provides the NIH the ability to monitor, mine, and develop its portfolio of taxpayer funded research more effectively.





Key Definitions





Open Access and NIH Public Access Policy

Open Access (OA) is scholarly material available online to the public free of charge, and free of most copyright and licensing restrictions.

NIH Public Access Policy is the submission of NIH funded, final, peer reviewed manuscripts to the National Library of Medicine's PubMed Central to be made freely available to the public.

Free PMC Article Free text

- > The NIH Policy is an example of Open Access.
- ➤ Open Access articles are not automatically compliant with the NIH Policy





PubMed and PubMed Central (PMC)

Free resources developed by the U. S. National Library of Medicine



- Database of biomedical journal citations, abstracts, and
- Links to some full text articles from PMC and publisher websites.
- Unique identifier: PMID followed by a series of numbers.



- Digital archive of full-text, peer-reviewed journal papers.
- Unique identifier: PMCID followed by a series of numbers.



Definitions



Final Peer-Reviewed Manuscript:

- Author's final manuscript of a peer-reviewed paper accepted for journal publication
- Includes all modifications from the peer review process
- Submitted by Authors and Publishers/Journals



Final Published Article

- Journal's authoritative copy of the paper
- Includes all modifications from peer review and the publishing process: copyediting, stylistic edits, and formatting changes
- Submitted by Publishers/Journals







How to Comply with the Policy



How Awardees Comply



1. Determine Applicability

2. Address Copyright

Institutions and investigators are responsible for ensuring full compliance with the Public Access Policy

3. Deposit Paper Upon Acceptance for Publication

- Four submissions methods (A-D) are available
- Methods A & B submit final journal articles to PMC
- Methods C & D submit final peer reviewed manuscripts to the NIH Manuscript Submission (NIHMS) system to be deposited in PMC

4. Cite Paper, include PMCID

Include the PMC number (PMCID) for applicable papers in applications, proposals and reports, see:
 http://publicaccess.nih.gov/citation_methods.htm.





1) Determine Applicability

Policy Applies to Any Final Manuscript That...

- Is peer-reviewed;
- Is accepted for publication in a journal on or after April 7, 2008;
- Arises from any direct funding from:
 - an NIH grant or cooperative agreement active in Fiscal Year 2008 or beyond, or;
 - an NIH contract signed on or after April 7, 2008, or;
 - the NIH Intramural Program, or;
 - an NIH employee.



OER

2) Address Copyright

Before an author signs a publication agreement or similar copyright transfer agreement, make sure that the agreement allows the final peer-reviewed manuscript to be submitted to NIH in accordance with the Public Access Policy.

Plan Ahead!

- What submission method will be used?
- What version of the paper will be made available on PMC?
- Who will submit the paper?
- When will it be submitted?
- Who will approve the submission?
- When can the paper be made public on PMC?





3) Posting papers to PubMed Central





How to Submit Manuscripts

- Four different submission methods are available, which vary in:
 - Version posted
 - Use of the NIH Manuscript Submission System (NIHMS)
 - Role of Publishers
 - Role of Authors
 - Participating Journals
- Authors may use the method that is most appropriate for them and is consistent with their publishing agreement.

http://publicaccess.nih.gov/submit_process.htm





PubMed Central Submission Methods

A

Journal¹ deposits the published version of all NIH-funded articles in PMC.

B

Author arranges with **Publisher**² to deposit published version of specific NIH-funded article in **PMC**.

Author confirms the article is deposited in PMC.

PubMed Central

C

Author or delegate submits final peer reviewed manuscript to the NIHMS.

NIHMS sends author an **email** asking author to approve the submitted materials for processing.

Author reviews and **approves** the PMC-formatted manuscript.



PubMed Central

D

Journal publisher submits final peer reviewed manuscript to the **NIHMS**. **NIHMS** sends author an **email** asking author to approve the submitted materials for processing.



- 1. See Journal list at http://publicaccess.nih.gov/submit_process_journals.htm#journals
- 2. See list of Publishers at http://publicaccess.nih.gov/select_deposit_publishers.htm
- 3. NIH Manuscript submission system (NIHMS)





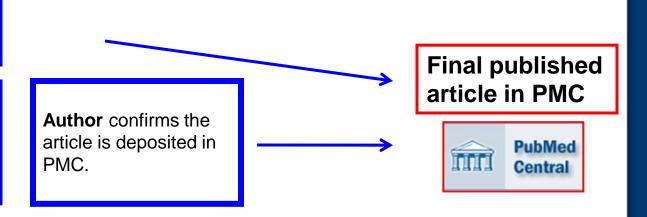
PubMed Central Submission Methods

A

Journal¹ deposits the published version of all NIH-funded articles in PMC.

B

Author arranges with **Publisher**² to deposit published version of specific NIH-funded article in **PMC**.



- ➤ **Method A Journals** (> 800) submit NIH-funded articles to PMC without author involvement.
- ➤ **Method B Publishers** deposit an individual article in PMC upon author request, generally for a fee.
- Final published article submitted to PMC at time of publication, assigned a PMCID
- Text available in PMC generally12 months after the date of publication



- 1. Journal list at http://publicaccess.nih.gov/submit_process_journals.htm#journals
 - 2. List of Publishers at http://publicaccess.nih.gov/select_deposit_publishers.htm



Methods C and D- Using the NIHMS

Who can deposit manuscripts in the NIHMS?

- > Author
- Delegate: anyone given access to the author's files: administrative personnel, graduate students, librarians, etc.
- > Publisher

Only **Authors** can approve of the submission and web version of the manuscript

Three steps to complete NIHMS submission process





Manuscript Submission to NIHMS

NIH Manuscript Submission system (NIHMS)

 Deposit manuscript files - NIHMSID created and sent to the submitter

Method C - submission by author or delegate **Method D** - submission by publisher



Author or delegate submits final peer reviewed manuscript to the NIHMS.

Journal publisher submits final peer reviewed manuscript to the **NIHMS**.

NIHMS sends author an **email** asking author to approve the submitted materials for processing.

NIHMS sends author an **email** asking author to approve the submitted materials for processing.

Author reviews and **approves** the PMC-formatted manuscript.







Manuscript Submission to NIHMS

2. Author approves PDF receipt, gives permission to NIH to process the manuscript.

Method C – at time of submission, author identifies PD/PI and NIH award(s), confirms copyright or permission, specifies delay period.

Method D – NIHMS email: author receives NIHMSID, identifies PD/PI and NIH award(s), approves PDF receipt/submission.

Author Approval



C

Author or delegate submits final peer reviewed manuscript to the NIHMS.

NIHMS sends **author** an email asking author to approve the submitted materials for processing.

Author reviews and approves the PMC-formatted manuscript.

D

Journal publisher submits final peer reviewed manuscript to the NIHMS.

NIHMS sends **author** an email asking author to approve the submitted materials for processing.









Author Manuscript Submission to NIHMS

3. Author approves PMC-formatted manuscript for public display: **Methods C and D**.

After submission is complete, NIHMS emails the citation with PMCID to author and PIs

Author Approval



Author or other submits final peer reviewed manuscript to the NIHMS.

NIHMS sends author an email asking author to approve the submitted materials for processing.

Author reviews and approves the PMC-formatted manuscript.



Journal publisher submits final peer reviewed manuscript to the NIHMS.

NIHMS sends author an email asking author to approve the submitted materials for processing.







4) Demonstrating Compliance with the Public Access Policy





Cite Articles Using PMC Numbers (PMCID)

Cite Paper

- When citing a paper in NIH applications, proposals, and progress reports, include the PMCID at the end of the full citation.
- This requirement only applies to papers that fall under the Policy and are authored or co-authored by you or arose from your NIH award.
- For more information see
 http://publicaccess.nih.gov/citation_methods.htm.

Example

Varmus H, Klausner R, Zerhouni E, Acharya T, Daar A, Singer P. 2003. PUBLIC HEALTH: Grand Challenges in Global Health. Science 302(5644): 398–399. PMCID: PMC243493





How to cite papers in press, or within 3 months of publication...

- For Method A and B Journals, use "PMC Journal In Process".
 - PMCIDs are assigned around the time of publication
 - "PMC Journal in process" is not acceptable 3 mo. after publication
 - Example: Sala-Torra O, Gundacker HM, Stirewalt DL, Ladne PA, Pogosova-Agadjanyan EL, Slovak ML, Willman CL, Heimfeld S, Boldt DH, Radich JP. Connective tissue growth factor (CTGF) expression and outcome in adult patients with acute lymphoblastic leukemia. *Blood.* [a publication date within 3 months of when the application, proposal or report was submitted to NIH]. PMCID: PMC Journal In Process
- For Method C and D Journals, use the NIHMSID.
 - NIHMSID is not acceptable 3 mo. after publication
 - Example: Cerrato A, Parisi M, Santa Anna S, Missirlis F, Guru S, Agarwal S, Sturgill D, Talbot T, Spiegel A, Collins F, Chandrasekharappa S, Marx S, Oliver B. Genetic interactions between *Drosophila melanogaster* menin and Jun/Fos. *Dev Biol*. In press. NIHMSID: NIHMS44135





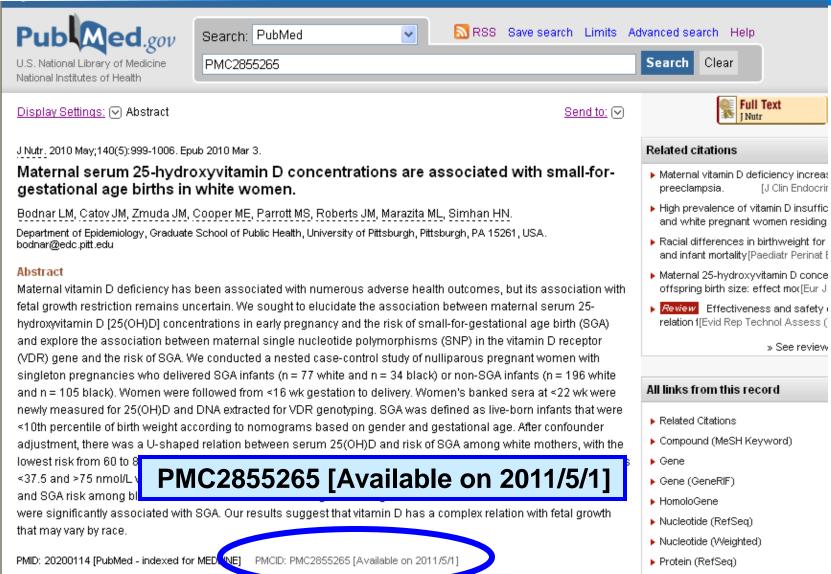


- Use PubMed
- Use MyNCBI (best approach)





Find PMCIDs in PubMed's Abstract View



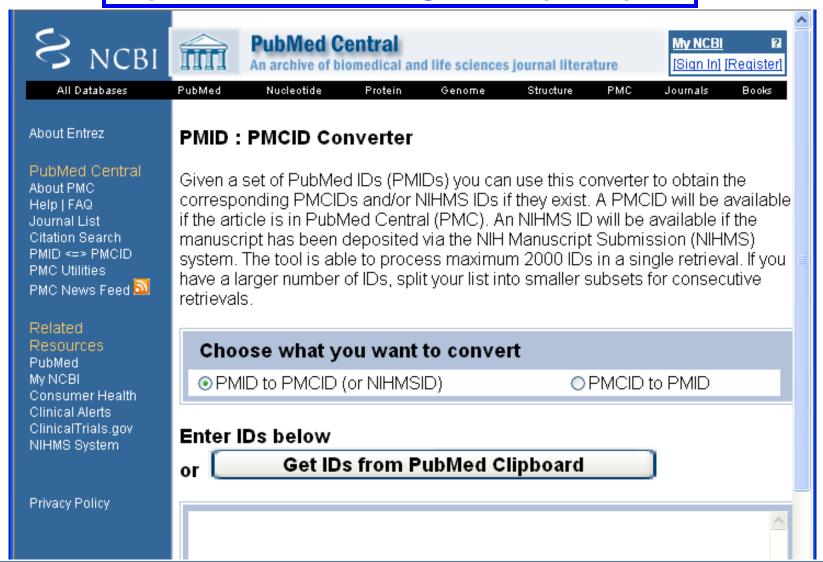
Publication Types MeSH Terms Substances Grant Support

Protein (Weighted)



PMID – PMCID Converter Tool

http://www.ncbi.nlm.nih.gov/sites/pmctopm







Using MyBibliography for Reporting and Tracking Compliance





eRA Commons - My Bibliography Integration

My NCBI Tool [My Bibliography] to Replace eRA Commons for Bibliography Management

NOT-OD-10-103 June 10, 2010

July 23, 2010: Commons will no longer support manual entry of

citations.

October 22, 2010: Commons will no longer display citations that were

manually entered into Commons

ACTIONS:

Establish a My NCBI account to access My Bibliography

- Link your eRA Common account to your My NCBI account
- Enter manually entered eRA Commons citations into My Bibliography
- Use the My NCBI My Bibliography to manage your citations and compliance with the NIH Public Access Policy (and/or delegate)





eRA Commons/ My Bibliography Integration

From the new Awards View [\$] in My Bibliography, eRA Commons users can:

- See if their publications are compliant with the NIH Public Access Policy
- Start the manuscript submission process
- Associate their NIH extramural grant awards with their publications

The **Awards View** is available only to Commons users with active grants in their portfolio who have linked their My NCBI account with their eRA Commons account.

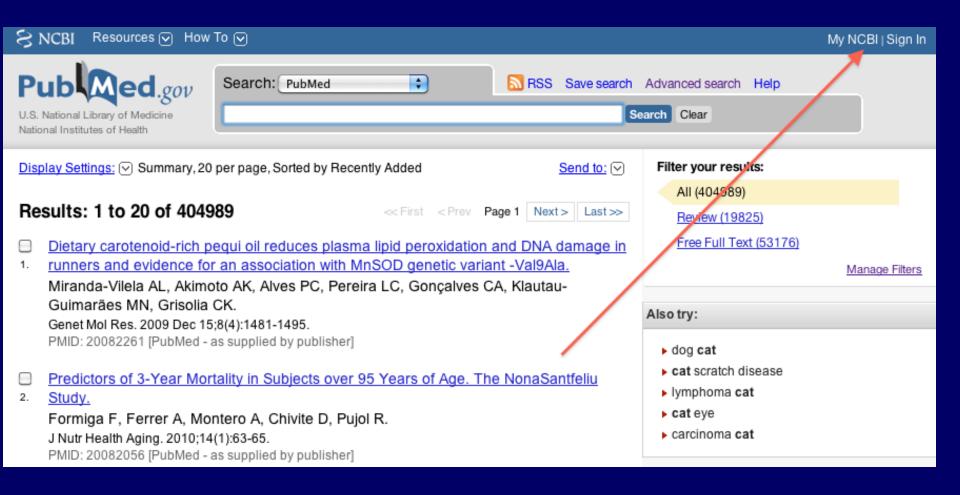


The My Bibliography NIH Public Access

compliance module

Bart Trawick, PhD
National Center for Biotechnology Information
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My NCBI Sign In



Federated Login



My NCBI allows you to create automatic email alerts, save your searches and records, filter results by subject, and much more.

Sign in directly to your My NCBI account:

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 Keep me signed in unless I sign out (Leave unchecked on public computers) Remember my username
Sign In
⊕ Register for an account
⊕ I forgot my username
⊕ I forgot my password
About automatic sign in

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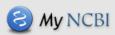
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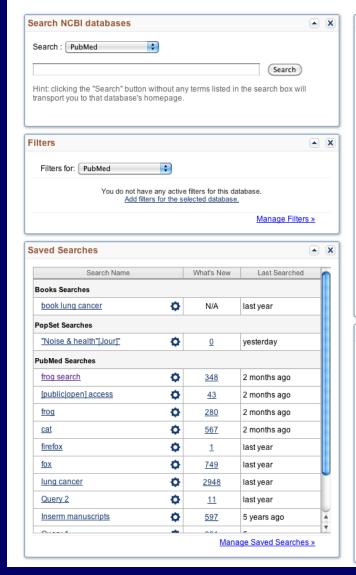
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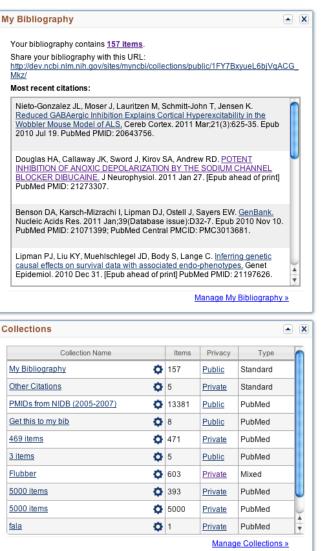
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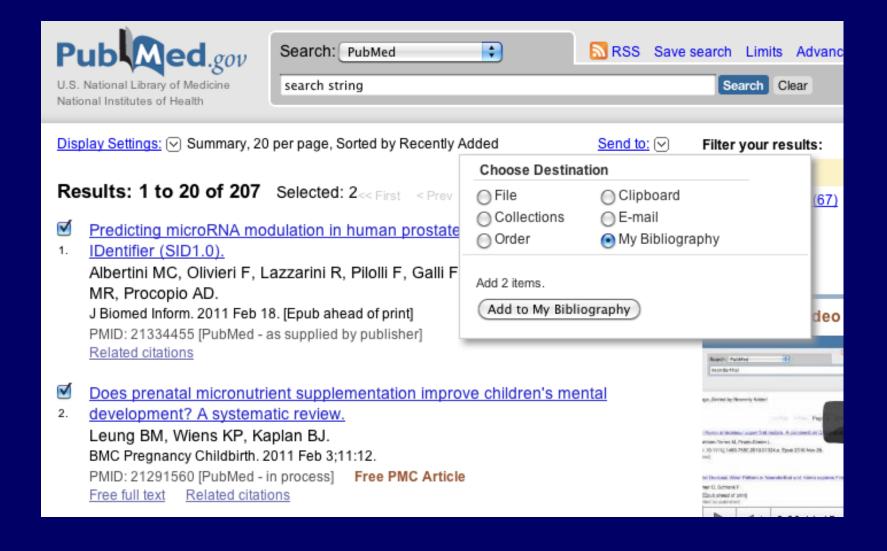




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- * Patents
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Adding PubMed Citations



Several Options to Add Non-PubMed Citations

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	C, Lauziere S, Xie Y, Poliard A, Qin C, Ward pe. J Bone Miner Res. 2010 Oct;25(10):2155-		
	gn-related risk factors for revision of primary c Central PMCID: PMC2917561.	emented stems. Acta Ortho	p. 2010 Aug;81(4):407-12. PubMed

Review Suggested Citations

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Suggestions t	for your Bibliography	
(+ Add	MEKC determination of IgG in human serum via a pH-mediated acid stacking method. Source: Suggested by prad178	\times
(+ Add	Point-of-care testing for interleukin-6 in cerebro spinal fluid (CSF) after subarachnoid haemorrhage Source: Suggested by prad178	<u>×</u>
(+Add)	Different inflammatory biomarker patterns in the cerebro-spinal fluid following heart surgery and management operations. Source: Suggested by prad178	ajor non-cardiac
+ Add	[Cerebro spinal fluid (CSF) leaks in ear: revision of 5 cases]. Source: Suggested by prad178	X
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+ Add	Papillary thyroid cancer presenting as Horner syndrome. Source: Suggested by prad178	X
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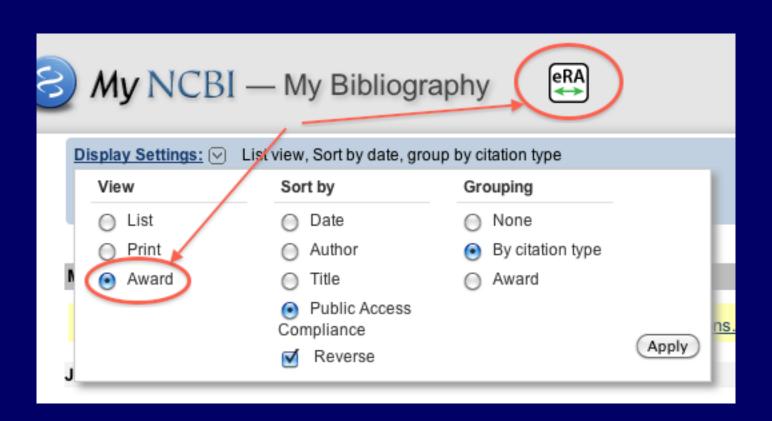
5: Chen L, Jiang W, Huang J, He BC, Zuo GW, Zhang W, Luo Q, Shi Q, Zhang BQ, Wagner ER, Luo J, Tang M, Wietholt C, Luo X, Bi Y, Su Y, Liu B, Kim SH, He CJ, Hu Y, Shen J, Rastegar F, Huang E, Gao Y, Gao JL, Zhou JZ, Reid RR, Luu HH, Haydon RC, He TC, Deng ZL. Insulin-like growth factor 2 (IGF-2) potentiates BMP-9-induced osteogenic differentiation and bone formation. J Bone Miner Res. 2010

Nov;25(11):2447-59. PubMed PMID: 20499340.

Review Match to PubMed Citation

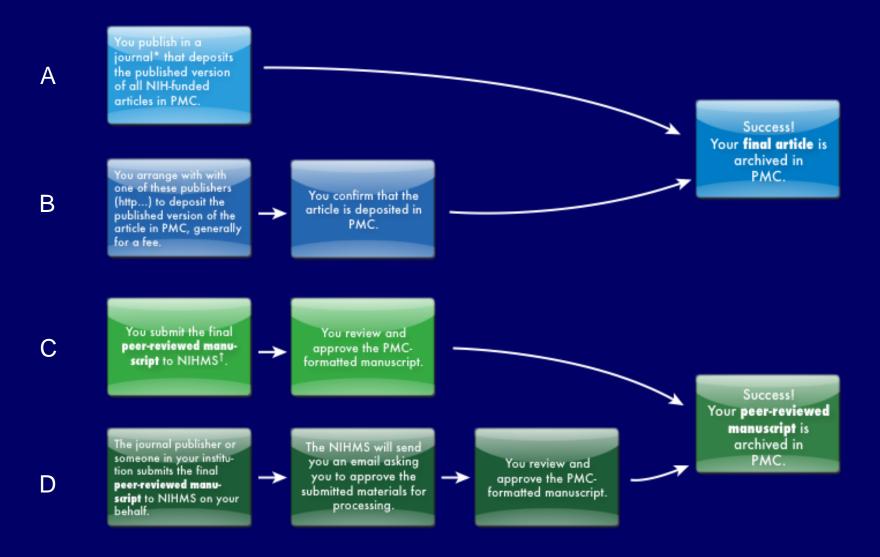
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NIH Public Access View



James RS. Effects of aestivation on skeletal muscle performance. Prog Mol Subcell Biol. 2010;49:171-81. PubMed PMID: 20069409.	Mohammed F. Screening for colorectal cancer. N Engl J Med. 2010 Jan 7;362(1):85; author reply 85. PubMed PMID: 20058342.
Public Access Compliance: Error: NIHMS ID: NIHMS does not exist NIH Funding: R01 AI044076-06 - TPN INDUCED CHANGES IN INTRAEPITHELIAL LYMPHOCYTES R01 AI044076-07 - TPN INDUCED CHANGES IN INTRAEPITHELIAL LYMPHOCYTES	 Public Access Compliance: Method B Journal - Pending PMC Submission NIH Funding: R01 AI044076-06 - TPN INDUCED CHANGES IN INTRAEPITHELIAL LYMPHOCYTES R01 AI044076-07 - TPN INDUCED CHANGES IN INTRAEPITHELIAL LYMPHOCYTES
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Public Access Compliance: Error: NIHMS ID: NIHMS has been removed. Please provide a new NIHMS ID. NIH Funding:	periodic follow-up testing among urban American Indian women with impaired fasting glucose. Prev Chronic Dis. 2008 Jul;5(3):A76. Epub 2008 Jun 15. PubMed PMID: 18558026; PubMed Central PMCID: PMC2483541.
R01 AI044076-06 - TPN INDUCED CHANGES IN INTRAEPITHELIAL LYMPHOCYTES R01 AI044076-07 - TPN INDUCED CHANGES IN INTRAEPITHELIAL LYMPHOCYTES	Public Access Compliance: Complete. PMCID: PMC2483541 NIH Funding: No funding has been associated with this citation.
Chen CC, Chen TF, Hwang YC, Wen YR, Chiu YH, Wu CY, Chen RC, Tai JJ, Chen TH, Liou HH. Different prevalence rates of Parkinson's disease in urban and rural areas: a population—based study in Taiwan. Neuroepidemiology. 2009;33(4):350-7. Epub 2009 Nov 4. PubMed PMID: 19887842.	─ Komáromy AM, Alexander JJ, Cooper AE, Chiodo VA, Glushakova LG, Acland GM, Hauswirth WW, Aguirre GD. <u>Targeting gene expression to cones with human cone opsin promoters in recombinant AAV.</u> Gene Ther. 2008 Jul;15(14):1049-55. Epub 2008 Mar 13. PubMed PMID: 18337838; PubMed Central PMCID: PMC2726772.
Public Access Compliance: Non-compliant. No PMCID 3 months post publication. NIHMS ID: NIHMS54654 NIH Funding:	Public Access Compliance: Complete. PMCID: PMC2726772 NIH Funding: No funding has been associated with this citation.
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R01 Al044076-11A1 - TPN Induced Changes in Intraepithelial Lymphocytes	Public Access Compliance: Complete. PMCID: PMC2488352 NIH Funding: No funding has been associated with this citation.
Kujawa SG, Liberman MC. Adding insult to injury: cochlear nerve degeneration after "temporary" noise-induced hearing loss. J Neurosci. 2009 Nov 11;29(45):14077-85. PubMe PMID: 19906956.	Huang Y, Koonin EV, Lipman DJ, Przytycka TM. <u>Selection for minimization of translational frameshifting errors as a factor in the evolution of codon usage</u> . Nucleic Acids Res. 2009 Nov;37(20):6799-810. Epub 2009 Sep 10. PubMed PMID: 19745054; PubMed Central PMCID PMC2777431.
Public Access Compliance: In process at NIHMS. (NIHMS ID: NIHMS163964) NIH Funding: R29 AI044076-04 - TPN INDUCED CHANGES IN INTRAEPITHELIAL LYMPHOCYTES	Public Access Compliance: Complete. PMCID: PMC2777431 NIH Funding: No funding has been associated with this citation.
Marom M, Hagalili Y, Sebag A, Tzvier L, Atlas D. Conformational changes induced in the voltage-gated calcium channels Cav1.2 by BayK 8644 or FPL-64176 modify the kinetics of secretion independently of Ca2+ influx. J Biol Chem. 2010 Jan 6. [Epub ahead of print] PubMed PMID: 20054004.	─ Wolf YI, Novichkov PS, Karev GP, Koonin EV, Lipman DJ. <u>Inaugural Article: The universal distribution of evolutionary rates of genes and distinct characteristics of eukaryotic genes of different apparent ages.</u> Proc Natl Acad Sci U S A. 2009 May 5;106(18):7273-80. Epub 2009 Apr 7. PubMed PMID: 19351897; PubMed Central PMCID: PMC2666616.
Public Access Compliance: PMC Journal - In Process NIH Funding: No funding has been associated with this citation.	Public Access Compliance: Complete. PMCID: PMC2666616 NIH Funding: No funding has been associated with this citation.

Four Ways to Comply with NIHPA



^{*}See list at: http://publicaccess.nih.gov/submit_process_journals.htm

[†]The NIH Manuscript Submission System (NIHMS) is located at https://nihms.nih.gov

Basic applicability NIH Funding

4:

7:

1. NIH Funding: Yes (edit)

Choose Your Awards That Funded This Citation (edit)

3. Public Access Compliance

The NIH Public Access Policy requires scientists to submit final, peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication. (See Determine Applicability for full details.) Please submit the final manuscript sent to your publisher or indicate that this publication is exempt from the policy.

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This citation has been submitted to NIHMS and is being processed. If this has changed, please make a new selection below.

Link to Method C/D

Start Method C

Claim Method B

Claim Exemption

- Begin submission in the NIHMS.
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 - Publication was not peer reviewed.
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Visual PA Status Codes

Public Access Compliance: Non-compliant. No PMCID 3 months post publication. NIHMS

ID: NIHMS70841

<u>NIH Funding:</u> No funding has been associated with this citation.

Public Access Compliance: PMC Journal – In Process
No funding has been associated with this citation.

Public Access Compliance: Complete. PMCID: <u>PMC2632597</u> <u>NIH Funding:</u> No funding has been associated with this citation.

NA Public Access Compliance: Not applicable

NIH Funding: No funding has been associated with this citation.

Public Access Compliance: <u>Edit Status</u>
<u>NIH Funding:</u> No funding has been associated with this citation.

Method A Examples

Marom M, Hagalili Y, Sebag A, Tzvier L, Atlas D. <u>Conformational changes induced in the voltage-gated calcium channels Cav1.2 by BayK 8644 or FPL-64176 modify the kinetics of secretion independently of Ca2+ influx.</u> J Biol Chem. 2010 Jan 6. [Epub ahead of print] PubMed PMID: 20054004.

Public Access Compliance: PMC Journal - In Process NIH Funding: No funding has been associated with this citation.

Komáromy AM, Alexander JJ, Cooper AE, Chiodo VA, Glushakova LG, Acland GM, Hauswirth WW, Aguirre GD. Targeting gene expression to cones with human cone opsin promoters in recombinant AAV. Gene Ther. 2008 Jul;15(14):1049-55. Epub 2008 Mar 13. PubMed PMID: 18337838; PubMed Central PMCID: PMC2726772.

Public Access Compliance: Complete. PMCID: PMC2726772 NIH Funding: No funding has been associated with this citation.

Method B Examples

Mohammed F. Screening for colorectal cancer. N Engl J Med. 2010 Jan 7;362(1):85; author reply 85. PubMed PMID: 20058342.

Public Access Compliance: Method B Journal - Pending PMC Submission NIH Funding:

R01 AI044076-06 - TPN INDUCED CHANGES IN INTRAEPITHELIAL LYMPHOCYTES

R01 AI044076-07 - TPN INDUCED CHANGES IN INTRAEPITHELIAL LYMPHOCYTES

Ances BM, Sisti D, Vaida F, Liang CL, Leontiev O, Perthen JE, Buxton RB, Benson D, Smith DM, Little SJ, Richman DD, Moore DJ, Ellis RJ; HNRC group. Resting cerebral blood flow: a potential biomarker of the effects of HIV in the brain. Neurology. 2009 Sep 1;73(9):702-8. PubMed PMID: 19720977; PubMed Central PMCID: PMC2734291.

Public Access Compliance: Complete. PMCID: PMC2734291 NIH Funding: No funding has been associated with this citation.

Method C/D Examples

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"temporary" noise-induced hearing loss. J Neurosci. 2009 Nov 11;29(45):14077-85. PubMed PMID: 19906956.

Public Access Compliance: In process at NIHMS. (NIHMS ID: NIHMS163964)
NIH Funding:

R29 AI044076-04 - TPN INDUCED CHANGES IN INTRAEPITHELIAL LYMPHOCYTES

Popa AS, Rabinstein AA, Huddleston PM, Larson DR, Gullerud RE, Huddleston JM. <u>Predictors of ischemic stroke after hip operation: a population-based study.</u> J Hosp Med. 2009 May;4(5):298-303. PubMed PMID: 19484726.

Public Access Compliance: Non-compliant. No PMCID 3 months post publication.

NIHMS ID: NIHMS168917

NIH Funding: No funding has been associated with this citation.

Krukenberg KA, Southworth DR, Street TO, Agard DA. <u>pH-dependent conformational</u> <u>changes in bacterial Hsp90 reveal a Grp94-like conformation at pH 6 that is highly active in suppression of citrate synthase aggregation.</u> J Mol Biol. 2009 Jul 10;390(2):278-91. Epub 2009 May 7. PubMed PMID: 19427321; PubMed Central PMCID: PMC2735500.

Public Access Compliance: Complete. PMCID: PMC2735500 NIH Funding:

R01 AI044076-08 - TPN INDUCED CHANGES IN INTRAEPITHELIAL LYMPHOCYTES R01 AI044076-09 - TPN INDUCED CHANGES IN INTRAEPITHELIAL LYMPHOCYTES

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Behbod F, Erwin-Cohen RA, Wang ME, Trawick BW, Qu X, Verani R, Kahan BD, Stepkowski SM, Kirken RA. Concomitant inhibition of Janus kinase 3 and calcineurin-dependent signaling pathways synergistically prolongs the survival of rat heart allografts. J Immunol. 2001 Mar 15;166(6):3724-32. PubMed PMID: 11238613.

N/A Public Access Compliance: Not applicable

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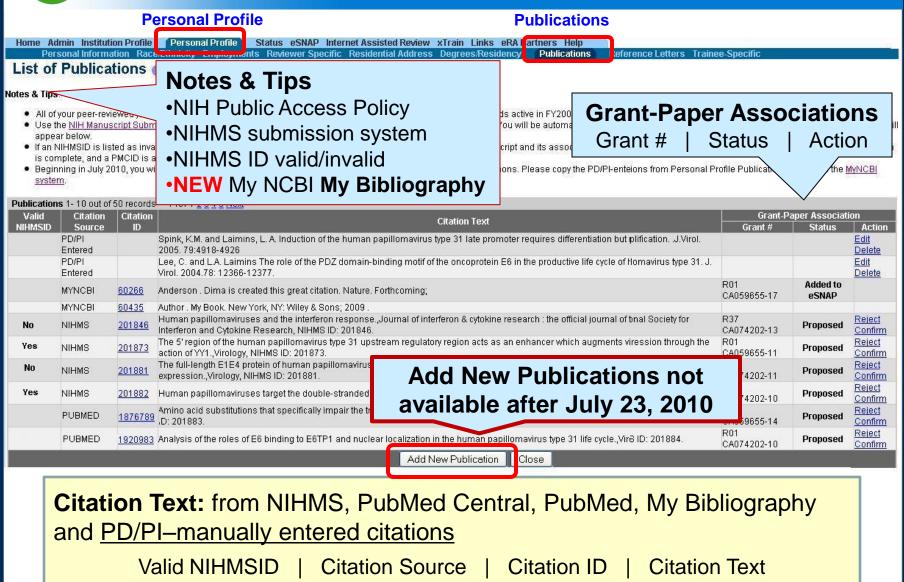
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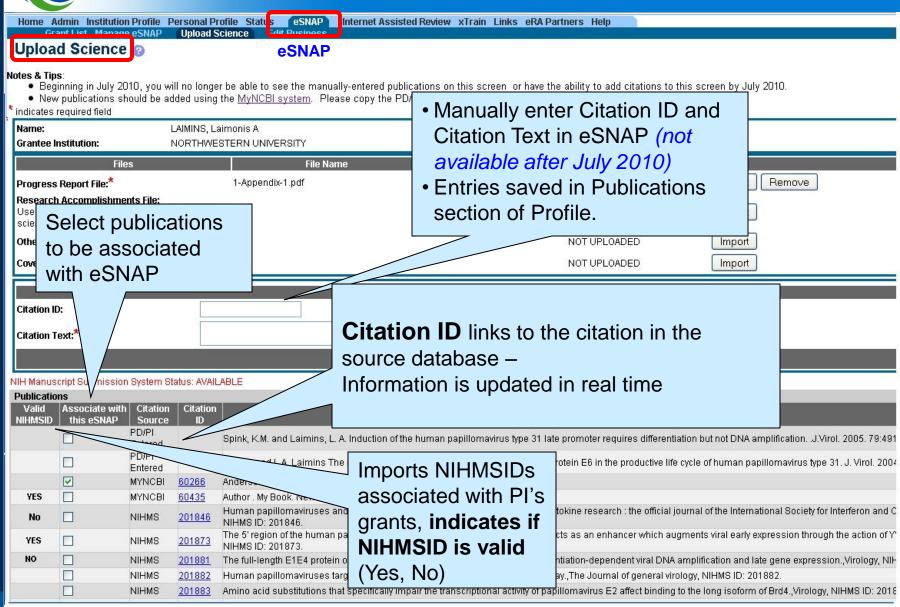
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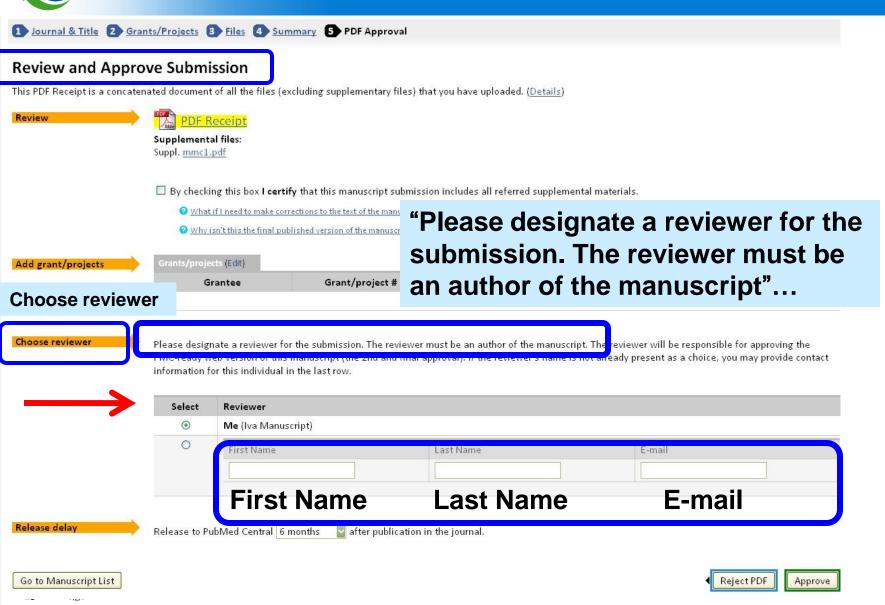
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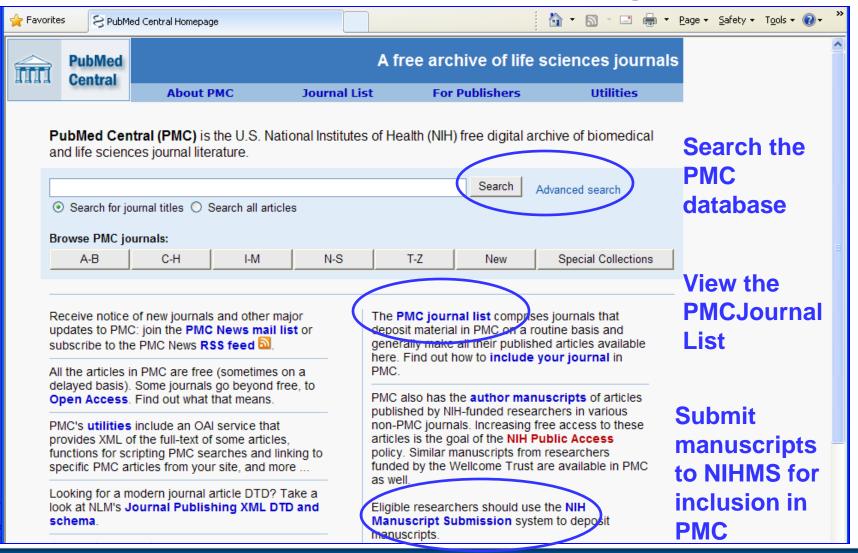
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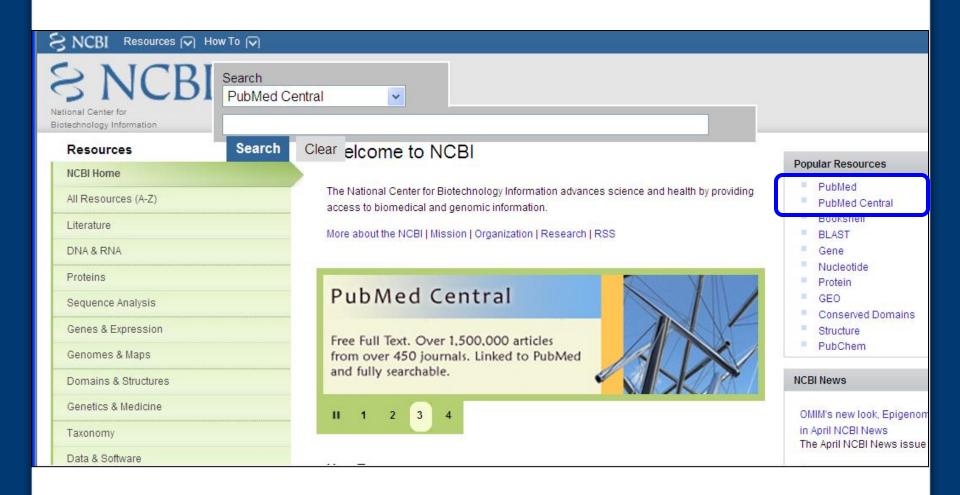
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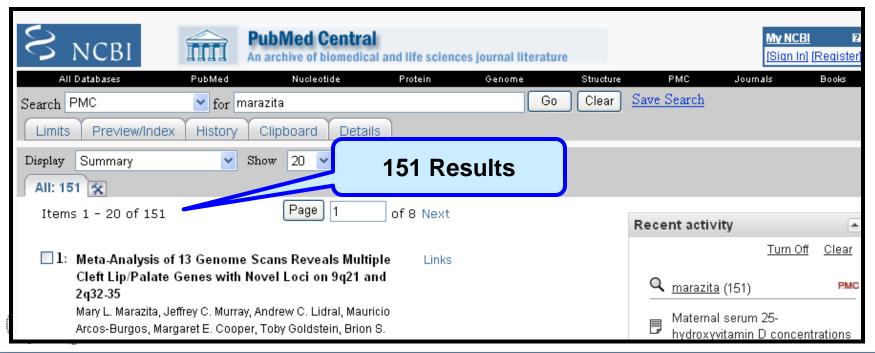






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Mary L. Marazita, Jeffrey C. Murray, Andrew C. Lidral, Mauricio Arcos-Burgos, Margaret E. Cooper, Toby Goldstein, Brion S. Maher, Sandra Daack-Hirsch, Rebecca Schultz, M. Adela Mansilla, L. Leigh Field, You-e Liu, Natalie Prescott, Sue Malcolm, Robin Winter, Ajit Ray, Lina Moreno, Consuelo Valencia, Katherine Neiswanger, Diego F. Wyszynski, Joan E. Bailey-Wilson, Hasan Albacha-Hejazi, Terri H. Beaty, Iain McIntosh, Jacqueline B. Hetmanski, Gökhan Tunçbilek, Matthew Edwards, Louise Harkin, Rodney Scott,

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Am J Hum Genet. 2004 August; 75(2): 161–173. Published online 2004 June 4.

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Genet Epidemio. Author manuscript; available in PMC 2010 May 1.

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Face shape of unaffected parents with cleft affected offspring: combining three-dimensional surface imaging and geometric morphometrics

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Meta-Analysis of 13 Genome Scans Reveals Multiple Cleft Lip/Palate Genes with Novel Loci on 9g21 and 2g32-35

Mary L. Marazita,^{1,2} Jeffrey C. Murray,³ Andrew C. Lidral,^{4,5} Mauricio Arcos-Burgos, Margaret E. Cooper, Toby Goldstein, Brion S. Maher, 1 Sandra Daack-Hirsch,³ Rebecca Schultz,³ M. Adela Mansilla,³ L. Leigh Field,^{7,8} You-e Liu,⁹ Natalie Prescott,¹⁰ Sue Malcolm,¹⁰ Robin Winter,¹⁰ Ajit Ray,¹¹ Lina Moreno,^{4,5} Consuelo Valencia,⁶ Katherine Neiswanger,¹ Diego F. Wyszynski,^{12,13} Joan E. Bailey-Wilson,¹⁴ Hasan Albacha-Hejazi,¹⁷ Terri H. Beaty,¹⁵ Iain McIntosh,¹⁶ Jacqueline B. Hetmanski,¹⁵ Gökhan Tunçbilek, 18 Matthew Edwards, 19 Louise Harkin, 22 Rodney Scott,20 and Laurence G. Roddick21

¹Center for Craniofacial and Dental Genetics, Division of Oral Biology, School of Dental Medicine, and ²Department of Human Genetics, Graduate School of Public Health, University of Pittsburgh, Pittsburgh; Departments of 3Pediatrics and 4Orthodontics and 5Dows Institute for Dental Research, University of Iowa, Iowa City; 6University of Antioquia, Medellín, Colombia; 7Department of Medical Genetics, University of British Columbia, and British Columbia Research Institute for Children's and Women's Health, Vancouver; 9Zhabei Genetics Institute, Shanghai; 10Clinical and Molecular Genetics Unit, Institute of Child Health, London; "Department of Anthropology (Emeritus). I Inivarcity of Toronto, Toronto, 12Ganatics Program, Danartment of Madicine, and 13Danartment of

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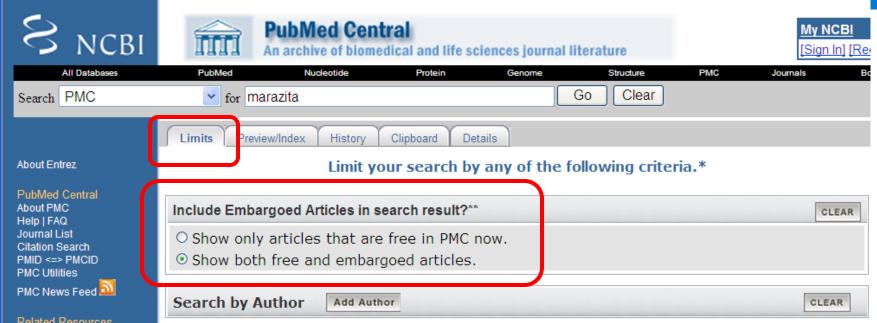
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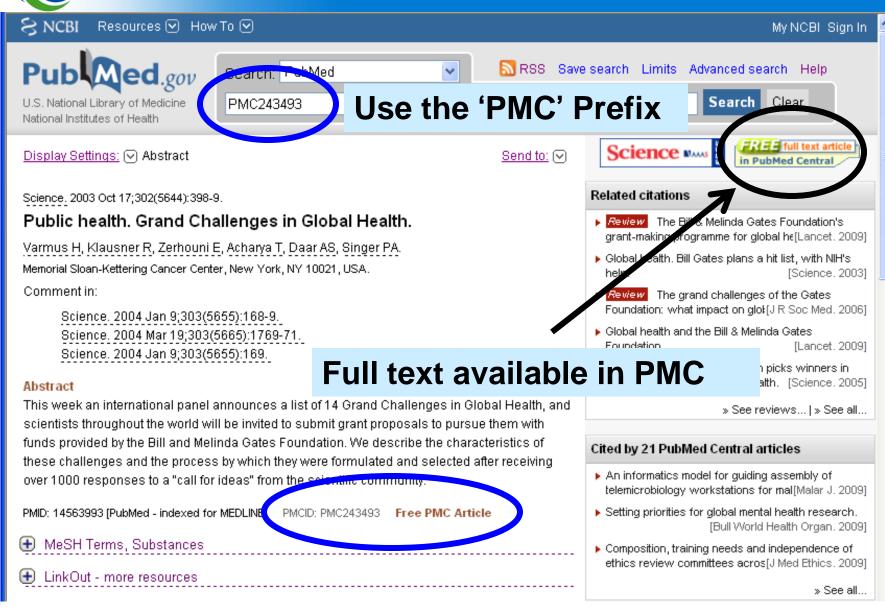
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PUBLIC HEALTH: Grand Challenges in Global Health

H. Varmus, R. Klausner, E. Zerhouni, T. Acharya, A. S. Daar, and P. A. Singer

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H. Varmus, R. Klausner, E. Zerhouni, T. Acharya, A. S. Daar, P.A. Singer

n 26 January 2003, at the World Economic Forum in Davos, Switzerland. Bill Gates announced a \$200-million medical research initiativethe Grand Challenges in Global Healthbased on a century-old model, the grand challenges formulated by the mathematician David Hilbert (1). Hilbert's list of important unsolved problems in mathematics (1) has spurred major research

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Gates Foundation (BMGF) on the assumption that, with greater encouragement and funding, contemporary science and technology could remove some of the obstacles to more rapid progress against diseases that disproportionately affect the developing world.

The efforts to identify Grand Challenges in Global Health relied on financial and administrative resources of two collaborating foundations, the BMGF and the Foundation for the National Institutes of Health (NIH); on a selection panel (scientific board) of 20 scientists and public health experts from 13 countries, including several from the developing world (2); and on the scientific community to supply ideas for challenges. In this Policy Forum, some of us involved in these events (H.V., R.K., and E.Z. as members of the Scientific Board's Executive Committee and P.A.S., T.A., and A.S.D. as scholars who provided support to the selection process) describe the deliberations that led up to this week's announcement of an initial list of Grand Challenges in Global Health (see table, page 399). We also outline the next steps that will be taken to fund research that addresses those challenges and plans to formulate additional grand challenges in subsequent years.

What Is a Grand Challenge?

On 1 May 2003, in a solicitation widely advertised in the developed and developing

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world, a grand challenge was described as "a call for a specific scientific or technological innovation that would remove a critical barrier to solving an important health problem in the developing world with a high likelihood of global impact and feasibility." Throughout the process of developing the grand challenges, the board struggled with how best to define them. A grand challenge is envisioned as distinct from a simple statement of one of the many "big problems" in global health, such as HIV/AIDS, malnutrition, the lack of access to medical care, or the lack of adequate resources. A grand challenge is meant to direct investigators to a specific scientific or technical breakthrough that would be expected to overcome one or more bottlenecks in an imagined path toward a solution to one or preferably several significant health problems. To satisfy this intent, a successful proposal would need to foresee a critical path of this type to get past a clearly defined roadblock. This formulation worked most effectively for those medical problems that are well enough understood to allow a description of what needs to be done, even if we do not yet know precisely how to do it. Thus, although the Grand Challenges initiative would ideally inspire unexpected and even radical solutions, the board also recognized the advantages of being able to envision solutions that have a high likelihood of being successful. The constraint of describing a "critical path past a bottle-neck" ruled out the broad field-building and exploratory research that usually underlies breakthroughs. Capacity building is another important approach (for example, increasing the number of biomedical research laboratories in the developing world, providing greater financial support for the study of global health or expanding professional training programs in global health) but beyond the purview of the program.

The scope of the initiative is broad, potentially encompassing many strategies for improving health through surveillance, prevention, detection, diagnosis, and treatment of diseases. Scientific disciplines underlying these strategies are also likely to be diverse. including immunology, microbiology, genetics. molecular and cellular biology, entomology, agricultural sciences, clinical sciences, epidemiology, population and behavioral sciences, and ecology and evolutionary biology. For example, control of pathogen-transmit-

ting insect vectors is likely to make a big difference in reducing the incidence of diseases such as malaria and dengue fever that are common in the developing world. Chemical interventions, e.g., insecticides, have been thwarted by the emergence of insecticide resistance and constrained by environmental concerns. Two of the selected grand challenges are meant to encourage the development of novel chemical or genetic strategies for rendering mosquitoes incapable of transmitting disease agents, without adverse ecological or other environmental effects (3).

How Were Grand Challenges Selected?

The announcement of the Call for Ideas on 1 May 2003, was accompanied by a dissemination campaign that included a Web site (4), advertisements in scientific journals, and email notifications, with the intent of engaging and eliciting ideas from scientists throughout the world. Between 1 May and 20 July, 1048 submissions were received from scientists and institutions in 75 countries. The large volume was gratifying but also required categorization according to topical content and the extent to which each submission met the criteria (4). The difference in number of proposals in various categories that met the criteria is reflected in the distribution of topics in the selected list of grand challenges.

The scientific board met on 17 and 18 August. To expedite discussion, the executive committee aggregated multiple, highly regarded, and closely related submissions into single proposals in advance of the meeting. The format chosen for presentation was the following: a brief statement of the background of the problem, followed by descriptions of the "roadblock" (the obstacle to progress) and the challenge itself, supplemented by lists of potential benefits, and, if appropriate, diseases or health conditions that are likely to be priority areas for study and application of findings. Each candidate was presented orally by two or more board members and then discussed by the full board. Wide participation was encouraged, so that ultimately all decisions were reached by oral consensus

Questions raised during the discussions reflected the criteria that the board had proposed earlier, but they also illustrated the difficulties of defining grand challenges in global health. Does the proposal describe a difficult and discrete roadblock to progress? What is the likelihood that creative solutions are required and that grant proposals worthy of funding will be received to address it? Is there already substantial scientific activity aimed at solving the problem, which would make the intent of a grand challenge redun-



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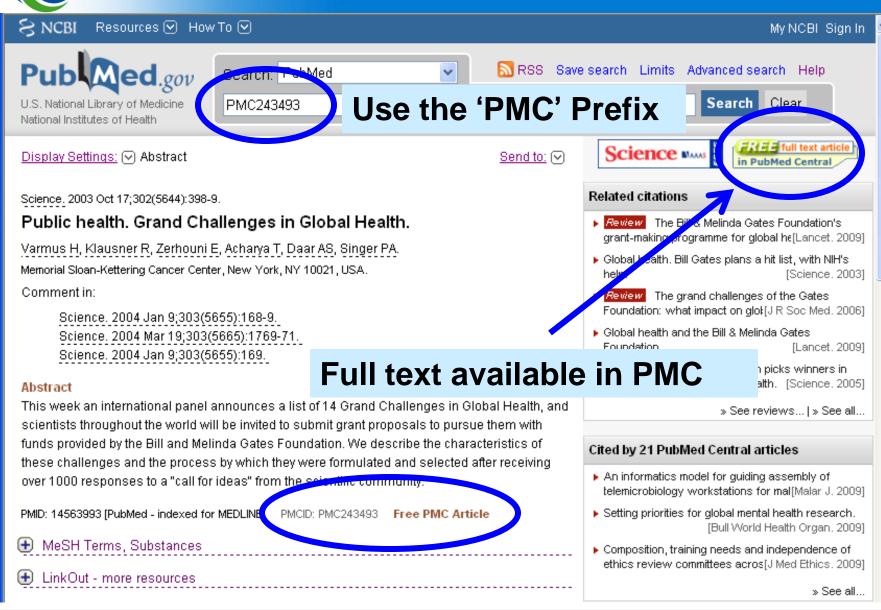
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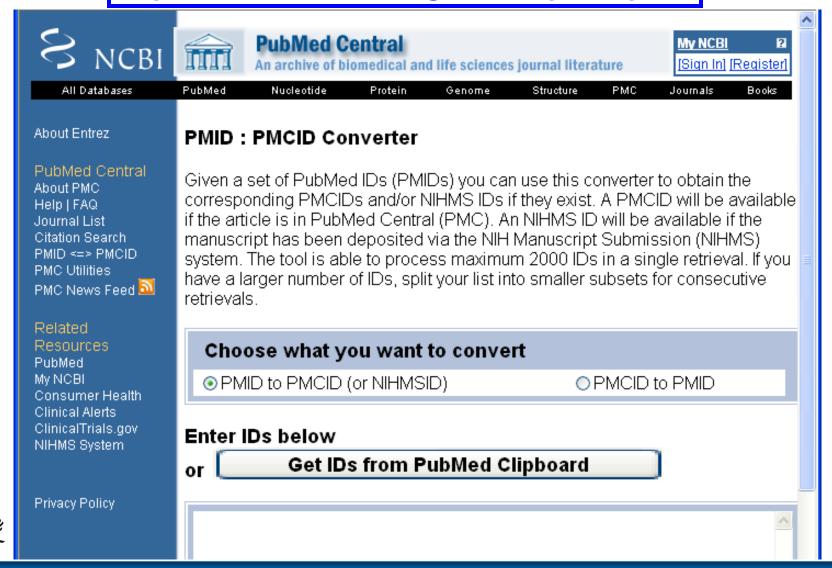
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Instructions: Citing Papers in NIH Applications





Part II - Overview of Application Instructions

Competing Applications

Submission Format	New Application	Renewal (in addition to requirements for new applications)	Biographical Sketch
SF 424 (R&R) Application Guide	Provide in Item 9 (Bibliography & References Cited) of the R&R Other Project Information a bibliography of any references cited in the Project Narrative and in the PHS 398 Research Plan component.	List publications and manuscripts accepted for publication and other printed materials that resulted from the project since last reviewed competitively in the Progress Report Publication List of the Research Plan.	Provide selected peer- reviewed publications or manuscripts in press in Section C of the Biographical Sketch upload of the R&R Senior/Key Person Profile.
SF 424 (R&R) Special Instructions Career Development Award Applications (CDA)	Provide in Item 9 (Bibliography & References Cited) of the R&R Other Project Information a bibliography of any references cited in the Project Narrative and in the PHS 398 Research Plan component.	Provide in the Progress Report Publication List of the Research Plan, a list of publications, manuscripts accepted for publication and other printed materials that resulted from the project since last reviewed competitively.	Provide peer-reviewed publications or manuscripts in press in Section C of the Biographical Sketch upload of the R&R Senior/Key Person Profile.





Competing Applications, Continued

Submission Format	New Application	Renewal (in addition to requirements for new applications)	Biographical Sketch
SF 424 (R&R) Supplemental Instructions for Institutional NRSA Award Applications	In item 9 Bibliography & References Cited of the R&R Other Project Information, cite references supporting the need, rationale, and approach for the training program described in the PHS 398 Research Training Program Plan. The Literature Cited section of the Research Plan is also captured in this section.	Provide Table 6 Publications of Research Completed by Trainees; include publications of trainees through the time that they complete their training for all trainees currently or previously supported by the training grant program.	For Program Director(s) and training faculty/ individuals who contribute significantly to the Research Training Program Plan, provide selected peer-reviewed publications or manuscripts in press in Section C of the Biographical Sketch upload of the R&R Senior/Key Person Profile. Biosketches of mentors and participating faculty are included in the PHS 398 Research Training Program Plan Component, Section 8.7 Item 12, Participating Faculty Biosketches.





Competing Applications, Continued

Submission Format	New Application	Renewal (in addition to requirements for new applications)	Biographical Sketch
SF 424 (R&R) Supplemental Instructions for Institutional NRSA Award Applications	In item 9 Bibliography & References Cited of the R&R Other Project Information, cite references supporting the need, rationale, and approach for the training program described in the PHS 398 Research Training Program Plan. The Literature Cited section of the Research Plan is also captured in this section.	Provide Table 6 Publications of Research Completed by Trainees; include publications of trainees through the time that they complete their training for all trainees currently or previously supported by the training grant program.	For Program Director(s) and training faculty/ individuals who contribute significantly to the Research Training Program Plan, provide selected peer-reviewed publications or manuscripts in press in Section C of the Biographical Sketch upload of the R&R Senior/Key Person Profile. Biosketches of mentors and participating faculty are included in the PHS 398 Research Training Program Plan Component, Section 8.7 Item 12, Participating Faculty Biosketches.





Competing Applications, Continued

Submission Format	New Application	Renewal (in addition to requirements for new applications)	Biographical Sketch
PHS 398 (6/2009)	Provide in the Bibliography and & References Cited section a bibliography of any references cited in the Project Summary and Relevance section, and in the Research Plan.	Provide in the Progress Report Publication List of the Research Plan, a list of publications, manuscripts accepted for publication and other printed materials that resulted from the project since last reviewed competitively.	Provide selected peer- reviewed publications or manuscripts in press in Section C of the Biographical Sketch.





Noncompeting Continuation Progress Reports

PHS 2590 (6/2009)	Report publications resulting directly from the grant that have not previously been reported, on Form Page 5 under a subheading E. Publications.
PHS 2590 CDA	Report publications resulting directly from the grant that have not previously been reported, on Form Page 5 under a subheading E. Publications.
PHS 2590 Institutional Training Grant	List all trainee publications not previously reported, including those by former trainees still in research training, on Form Page 5, under C. Trainees.
eSNAP	When an eRA Commons eSNAP is initiated, a list of publications is automatically pulled into the Upload Science screen, for potential inclusion in the progress report, from two sources. First, eRA Commons pulls citations from the NIH Manuscript Submission system (including the appropriate PMCIDs and NIHMSIDs) that can be attributed to any PD/PI identified on the Notice of Award. Second, the list contains all manual entries from the Publications section of all PDs/PIs Personal Profiles. These manual entries are displayed with the Citation Source of "PD/PI Entered" both within the eSNAP and within the Publications section of the user's Personal Profile. Users must carefully review the publication list and "check" the checkbox of all citations to be associated with the report. The eSNAP user also has the option to manually add additional citations from within eSNAP. When manually entering citations, users should include the appropriate identifier as described above under Demonstrating Compliance. It is important to verify that the NIH Manuscript Submission System Status shows "AVAILABLE" on the Upload Science page when preparing and submitting the eSNAP report to ensure that all appropriate citation information is included in the report.
PHS 416-9 Individual Fellowship (6/2009)	List publications on Form Page 2 under 16.B. Progress.





Guide Notice – Final Progress Reports

Final Progress Reports

Prepare report in accord with instructions provided by awarding component.	Include a list of publications resulting from the project, with plans, if any, for further publications. See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-051.html .
PHS 416-7 NRSA Termination Notice (trainees and fellows)	List any publications resulting from research during the period of the training in block 8 on form 416-7.

